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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,453	09/13/2000	Steven M. Ruben	PZ038P1	8927

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EXAMINER
MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
1631	17

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/661,453	Applicant(s) Ruben et al.
	Examiner Ardin Marschel	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Apr 9, 2003*

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *24-36, 39-43. 46-50, 53-57, and 60-73* is/are pending in the application.

4a) Of the above, Claim(s) *1-23,37,38,44,45,51,52,58, & 59 have been canceled* [illegible] from consideration.

5) [X] Claim(s) *24, 28-30, 34, and 35* is/are allowed.

6) [X] Claim(s) *25-27, 31-33, 36, 39-43, 46-50, 53-57, and 60-73* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [X] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [X] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) [ ] Interview Summary (PTO-413) Paper No(s). _____
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other:

Applicants' arguments, filed 4/9/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 25 and 31 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained and reiterated from the previous office action, mailed 1/9/03. Applicants argue that applicant must blaze marks on trees rather than simply providing the public with a forest of trees. This supports the rejection in that blaze marks on trees are required which supports the written description requirement as requiring specific Methionine lacking as amino acid residue 1 specifically regarding the claimed SEQ ID NO: 73 which is not disclosed specifically as filed thus supporting this rejection. Applicant then argue that the same terms may not be utilized to describe an invention. In response this is acknowledged but the specific Methionine removal or lack for SEQ ID NO: 73 is not an issue regarding terms or

equivalents but a lacking written description thus again supporting this rejection. Applicant then argues that the burden of evidence or reasons to support this rejection has not been met. In response the lack of written basis for the Methionine lack in SEQ ID NO: 73 has been set forth as clear evidence or reasons and thus this argument is moot, including the acknowledgment that applicants have not pointed to such a Methionine missing SEQ ID NO: 73 specifically as filed. Applicants then argue that one skilled in the art would reasonably conclude that applicants had possession of the claimed invention. This argument is moot in that it is not directed to the basis of the rejection which is the lack of written description and not what reasonably could be concluded. Applicants then point to pages 150-151 as applying to all polypeptide of the invention regarding post-translational modifications of polypeptides. Consideration of said pages reveals that the bridging paragraph on pages 150-151 list such modifications but indicate that these "may" include such modifications and that the N-terminal methionine is "generally" removed with "high efficiency". These descriptions are neither specific for SEQ ID NO: 73 nor do they "require" or specifically disclose the actual N-terminal removal of a Methionine from any particular polypeptide. The phrase "high efficiency" clearly lacks a disclosure of total removal of N-terminal methionine in

eukaryotic cells and thus fails to specifically focus on any specific polypeptide, much less, the polypeptide described via SEQ ID NO: 73. Applicants appear to be attempting to change what is possible, or even likely, into something inherently disclosed. This attempt lacks the specific written basis as required under 35 U.S.C. 112, first paragraph.

LACK OF SCOPE OF ENABLEMENT

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-27, 31-33, 36, 39-43, 46-50, 53-57, and 60-73 are rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is only supported as to usage regarding a polypeptide consisting only of the entirety of SEQ ID NO: 73, one skilled in the art would not know how to use the claimed invention directed to fragments thereof.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue

experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

This rejection is maintained and reiterated from the previous office action, mailed 1/9/03. As stated in said previous office action, this rejection is no longer directed to the polypeptide consisting of the entirety of the amino acids of SEQ ID NO: 73 per se, but still is maintained against other polypeptides which are fragments thereof or some type of conjugate or fusion protein which is included in the instantly pending claims, albeit some narrowed with consisting of wording, the portion of this rejection directed to non-SEQ ID NO: 73 limitations is maintained. The above claims still contain embodiments beyond SEQ ID NO: 73 in its entirety. It is noted that claims such as 36 etc. as argued by applicants have been narrowed with said consisting of wording but still contain the

non-SEQ ID NO: 73 sequence via broadening limitations directed to percentage of identical sequence and heterologous segments. Applicants argue that undue experimentation would not be required to determine which proteins would be useful regarding immunogenicity. In response this allegation is not based on finding a series of useful embodiments as in the legal decision of *In re Wands* but rather only on the allegation that finding usefulness for one single sequence, that is, SEQ ID NO: 73 that then all similar including arbitrary percentages of dissimilarity are also useful regarding immunogenicity. Thus, the series of useful embodiments as found in *In re Wands* is a different fact pattern from that of the instant application and thus non-persuasive.

LACK OF WRITTEN DESCRIPTION

Claims 25-27, 31-33, 36, 39-43, 46-50, 53-57, and 60-73 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."*Lockwood v.*

American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention."*Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms, "requires a precise definition, such as by structure, formula, chemical name, or physical properties,"not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The above requirement for written description reasonably also applies to protein as instantly claimed. While the instant specificaion provides a process for obtaining polypeptides with

immunogenicity, there is no further information pertaining to polypeptide relevant structural or physical characteristics; in other words, it thus does not describe specific immunogenic polypeptides other than that described by SEQ ID NO: 73. Describing a method of preparing a polypeptide or protein or even describing the protein by sequence identity, as the claims do, does not necessarily describe the protein or polypeptide itself. No sequence information indicating which amino acids appears to be in immunogenic polypeptides are set forth in the instant specification. Accordingly, the specification does not provide a written description of the invention beyond a polypeptide described via SEQ ID NO: 73.

Claims 24, 28-30, 34, and 35 are allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 24, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER